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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,593	11/29/2001	Seiji Sakano	KP8447DIV	2953

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,593	SAKANO ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *89-91 and 101-118* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *89-91, 101-118* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/22/2005 has been entered.

2. Claims 1-88, 92-97 have been canceled previously. Claims 98-100 have been canceled in the amendment filed 11/22/2005. Claims 89-91 and new claims 101-118 are pending in the instant application and are under consideration by the Examiner.

3. Receipt of applicant's arguments and amendments filed on 11/22/2005 is acknowledged.

4. The following previous rejections and objections are withdrawn in light of Applicants amendments filed on 11/22/2005:

(i) the rejection of claims 89-91 under 35 U.S.C. § 112, second paragraph.

5. Applicant's arguments filed on 11/22/05 have been fully considered but were persuasive in part. The issues remaining and new issues are stated below.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. The disclosure is objected to because of the following informalities:

The specification is replete with grammatical and spelling errors. For example, page 48, line 24 recites "molecular" rather than "molecule".

Appropriate correction is required.

Claim rejections-35 USC § 112, first paragraph

8a. Claims 89-91, 101-106, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained for reasons of record set forth at pages 2-3 of the previous Office action (8/30/04) and pages 2-3 of the previous Office action (3/24/05).

Applicants argue that from Examples 10, 11, 12, in the specification, it can be concluded that differentiation suppression can be extrapolated or inferred. Applicants also argue that the colony assay in Example 10 correlates to the assays in the Gordon (1993) reference, at page 191 in the reference. However, contrary to Applicants arguments, Gordon , on page 191, discloses that "The colonies can be analyzed morphologically and by replating the cells they contain into different clonogenic systems to obtain information about the self-renewal and differentiation potential of the colony-forming progenitor." The assays described in Example 10, indicate suppression of colony formation. The differentiation suppression potential of the serrate-1 peptide has not been determined or analyzed. Differentiation and proliferation are disparate

processes and when proliferation is obtained, it cannot be extrapolated to indicate differentiation. Stedman's Medical Dictionary, 25th edition, page 434, defines "differentiation" as "specialization; the acquisition or possession of one or more characteristics or functions different from that of the original type". Therefore, suppression of differentiation would be loss of acquisition or possession of one or more characteristics or functions different from that of the original type, and this quality has not been demonstrated by Applicants in Example 10. Furthermore, Examples 11 and 12, also demonstrate that serrate-1 inhibits colony formation.

It is unclear from the specification, Example 10, lines 3-4, whether the blood undifferentiated cells which are CD34 positive cells are "stem cells" because differentiation is obtained when stem cells differentiate, for example cancer cells are dedifferentiated cells. The passage recited from the Gordon reference, at page 191, is true about using clonogenic assays to obtain information about proliferation and differentiation. However, the issue here is that in the instant application only proliferation of colonies has been shown (see Figures 2A and 2B). The instant specification does not reveal any results regarding differentiation of the cells in the colonies.

It is unclear from Examples 10-12, whether the starting materials for the experiments were stem cells. In addition, all that has been demonstrated in these Examples is an increase in the number of colonies not in the differentiation of these cells. For example, in Figure 2A if the cells utilized in the assay are stem cells, and these control stem cells (in the absence of serrate-1 protein) show 10 differentiated cells and in the presence of serrate-1 the number of differentiated cells is suppressed, this result would indicate that serrate-1 suppresses differentiation in the stem cells. However, this is not a result or conclusion that can be obtained from the instant

specification. The burden of demonstrating differentiation of the cells is on Applicants and Applicants have failed to demonstrate differentiation of blood precursor cells.

8b. Claims 89-91, 101-118, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for suppressing colony formation of blood precursor cells in vitro, comprising contacting said cells in vitro with a serrate-1 peptide and stem cell factor (SCF), thereby suppressing colony formation, and wherein said serrate-1 peptide is selected from the group consisting SEQ ID NO: 5, SEQ ID NO: 6, and SEQ ID NO: 7, does not reasonably provide enablement for a method as recited in claim 89 further comprising contacting the cells with IL-3, IL-6, EPO and G-CSF. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

With respect to the limitations recited in claim 101, for example, the claim recites a method comprising contacting cells with serrate–1 peptide and any of SCF, IL-3, IL-6, EPO and G-CSF. However, the specification, page 48, lines 27-28, explicitly recites "Comparison with or without SCF on the activity indicated that the suppressive action tended to occur only in the presence of SCF".

While the specification explicitly discloses that the suppressive action of serrate-1 occurred only in the presence of SCF, the claims are broader than the supporting disclosure because they fail to recite that the suppressive action of serrate-1 occurs only in the presence of SCF. One would not have a reasonable expectation of successfully using the serrate-1 peptide in the method consistent with the scope of the claims.

The specification discloses the effect of the serrate-1 peptide on suppressing colony formation of blood precursor cells in vitro, in the absence of SCF (Example 10). However, the claims recite a method comprising administering serrate-1 peptide on suppressing colony formation of blood precursor cells in vitro. The instant specification is non-enabling for such a method because the ability of serrate-1 alone to suppress colony formation would not be an enabled paradigm. The serrate-1 peptide could not be administered with a predictable prognosis using the specification as guidance because the specification provides no examples nor is an enabling mechanism disclosed using the serrate-1 peptide alone or serrate-1 in combination with one of IL-3, IL-6, EPO or G-CSF, commensurate with the scope of the claims. In the absence of such a disclosure a skilled artisan would be unable to practice the method embraced by the claims without undue experimentation.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
December 12 , 2005